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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,475	09/10/2003	Lance Schlipalius	M 5767A-NHG/CA	3437

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COGNIS CORPORATION
PATENT DEPARTMENT
300 BROOKSIDE AVENUE
AMBLER, PA 19002

EXAMINER	
KIM, JENNIFER M	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/659,475	SCHLIPALIUS ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/16/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 16, 2006 has been entered.

Action Summary

The rejection of claims 1, 3-5, 14 and 15 under 35 U.S.C. 102(e) as being anticipated by Akamatsu et al. (U.S.Patent No. 5,780,056) evidenced by Ogawa et al. (U.S.Patent No. 5,004,756) is maintained for the reasons stated in the previous Office Action.

The rejection of claims 6-13 and 16 under 35 U.S.C. 103(a) as being unpatentable over Akamatsu et al. (U.S.Patent No. 5,780,056) is maintained for the reasons stated in the previous Office Action.

Response to Arguments

Applicants' arguments filed February 16, 2006 have been fully considered but they are not persuasive. Applicants essentially argue the subject matter of claim 1 is not identically disclosed by Akamatsu even though Akamatsu discloses lycopene as a carotenoids and MTC as a triglyceride, there is no disclosure whatsoever or a medium-chain length triglyceride derived from esterification of a substantially pure medium chain fatty acid and substantially pure glycerol which maintains the concentration of lycopene for at least three moths at 25 °C. This is not persuasive because Akamatsu et al. teaches all the required elements of Applicant's instant claim 1. Akamatsu teaches that Applicants' carotenoids composition comprising lycopene suspended in medium chain triglyceride (having 8-12 carbon atoms (such as caprylic acid, capric acid and lauric acid) and the amounts of antioxidants blended in an effective amounts encompassing Applicants claimed amounts in claims 14 and 15. Even though product-by-process of utilized medium-chain triglyceride are limited by and defined by the process, determination of active component is based on the product (medium-chain triglyceride) itself. It is noted their physical structural characteristic as being a **medium-chain triglyceride** remains the same. Therefore, the effect of maintaining the concentration of lycopene for at least three months at 25°C is inherent.

In view of the above Office Action of June 22, 2005 is deemed proper and asserted with full force and effect herein to obviate applicants' claims.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1, 3-5, 14 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Akamatsu et al. (U.S.Patent No. 5,780,056) evidenced by Ogawa et al. (U.S.Patent No. 5,004,756).

Akamatsu et al. on column 3, lines 5 through 40, teach Applicants' carotenoid composition comprising lycopene suspended in medium chain triglyceride (having 8-12 carbon atoms (such as caprylic acid, capric acid and lauric acid)). Akamatsu et al. teach the antioxidant is blended in an effective amount, typically 0.01 to 15% by weight based on the weight of the microcapsule, which encompasses the amounts set forth in claims 14 and 15. (column 3, lines 57-59).

Applicants' limitation of effect of maintaining the concentration of lycopene for at least three months at 25°C does not distinguish from the composition taught by Akamatsu et al. because Akamatsu et al. teaches same active agents required by the Applicant's claims 1 and 16 and therefore the effect would be inherent.

Ogawa et al. disclose that triglycerides of medium-chain fatty acid have 8-12 carbon atoms (such as caprylic acid, capric acid and lauric acid), and normally abbreviated as MCT.

Ogawa et al. is brought in as an extrinsic evidence to show that medium-chain fatty acid utilized by Akamatsu et al. are well-known by Ogawa et al. as having 8-12 carbon atoms (such as caprylic acid, capric acid and lauric acid) as claimed by Applicants.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 6-13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akamatsu et al. (U.S.Patent No. 5,780,056).

Akamatsu et al. as applied as above and additional teaching as follows.

Akamatsu et al. on column 3, lines 5 through 40, teach Applicants' carotenoid composition comprising lycopene suspended in medium chain triglyceride. Akamatsu et al. report that lycopene has anti-carcinogenic activity. (column 3, lines 25-32). Akamatsu et al. teach that the antioxidants to be utilized in the composition include tocopherol. (column 3, lines 47-50). Akamatsu et al. also teach on column 2, lines 5-17 that their composition is provide high strength of carotenoids to prevent the carotenoids from being oxidized or deteriorated for a long time and in a stable manner. Akamatsu et al. teach the effective amount of 0.01 to 15% by weight, which encompasses the amounts set forth in claims. Akamatsu et al. teach that the amount of carotenoids and edible oil (medium chain triglyceride) are mixed in a weight ratio between 20/80. (column 3, lines 40-43).

The difference between above reference and Applicants' claimed invention is to administer Akamatsu's composition to the host to provide a bioavailable antioxidant (lycopene) and the amounts of lycopene.

However, the skilled artisan would have been motivated to employ Akamatsu's composition to a host i.e. cancer patients, to benefit its delivery of high strength of lycopene which is not vulnerable to oxidation and deterioration in the treatment of cancer. The amounts of active agents (lycopene) to be used, the pharmaceutical forms, e.g., tablets, etc; mode of administration, flavors, surfactant, types of tocopherol to be selected are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and Akamatsu et al. teach the tocopherol in general therefore it encompasses any one of the tocopherol including alpha, beta and delta.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
March 3, 2006